

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1250 (June 2002).

Chapter 15. Current Good Manufacturing Practices in the Manufacture of Drugs

§1501. Definitions

[formerly paragraph 6:191]

A. Unless otherwise specifically provided herein, the following words and terms used in this Part of the Sanitary Code, and all other Parts which are adopted or may be adopted, are defined for the purposes thereof as follows.

Active Ingredient Any component which is intended to furnish pharmacological activity or other direct effect in the diagnosis, care, mitigation, treatment or prevention of disease or to affect the structure of any function of the body of man or other animals. The term shall include other components which may undergo chemical change in the manufacture of the drug or be present in the finished product in a modified form intended to furnish the specified activity or effect.

Batch A specific quantity of a drug that has uniform character and quality within specified limits, and is produced according to a single manufacturing order.

Component Any ingredient intended for use in the manufacture of drugs in dosage form, including those that may appear in the final product.

Factory See Chapter 1, §101 of this Part.

Inactive Ingredient Any component other than an Active Ingredient present in a drug.

Lot A batch or any portion of a batch of a drug or, in the case of a drug manufactured in a continuous process, an amount of drug product in a unit of time or quantity in a manner that assures its uniformity and in either case which is identified by a distinctive lot and has uniform character and quality within specified limits.

Lot Numbers or Control Numbers Any distinctive combination of letters or numbers, or both from which the complete history of the manufacture, control, packaging and distribution of a batch or lot of drug can be determined.

Materials Approval Unit Any organizational element having the authority and responsibility to approve or reject components, in processing materials, packaging components and final products.

Strength

a. the concentration of the drug substance (for example: w/w, w/v or unit dose/volume basis); and/or

b. the potency, that is the therapeutic activity of the drug substance as indicated by appropriate laboratory test or by adequately developed or clinically controlled data expressed (for example: in terms of units by reference to a standard).

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§1503. Permits

[formerly paragraph 6:192]

A. No person shall operate any factory or process or repackage any drug within the State of Louisiana, without first applying for, paying the required fee and obtaining a permit to operate, issued by the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1251 (June 2002).

§1505. Public Display of Permits

[formerly part of paragraph 6:192]

A. Every establishment regulated by this Part shall have displayed, at all times, in a place designated by the state health officer, a permit to operate.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1251 (June 2002).

§1507. Permit Exemptions

[formerly paragraph 6:193]

A. The following shall be exempt from the above permit procedures.

1. [Formerly paragraph 6:193-1] Pharmacies that are operating under applicable State laws regulating the dispensing of prescription drugs and that do not manufacture, prepare, propagate, compound or process drugs for sale other than in the regular course of the profession of pharmacy including the dispensing and selling of drugs at retail.

2. [Formerly paragraph 6:193-2] Hospitals, clinics and public health agencies which maintain establishments in conformance with any applicable State laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, other than human blood products, upon prescription of practitioners, licensed by law to administer such drug for patients under the care of such practitioners in the course of their professional practice; practitioners who are licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound or process drugs solely for use in the course of their professional practice; and manufacturers of harmless inactive ingredients which are excipients, colorings, flavoring, emulsifiers, lubricants, preservatives or solvents that become components of drugs.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1251 (June 2002).

§1509. Examination, Condemnation and Destruction of Unwholesome or Adulterated Drugs
[formerly paragraph 6:194]

A. Samples of drugs and drug components may be taken and submitted to a state approved laboratory by the state health officer for examination as often as he deems necessary for the detection of unwholesomeness or adulteration. The state health officer may condemn and forbid the sale of, or cause to be removed or destroyed, any drug which he deems unwholesome or adulterated.

AUTHORITY NOTE: Promulgated in accordance with the provisions of §258(B) of Title 36, and Chapters 1 and 4 of Title 40 of the Louisiana Revised Statutes of 1950. See in particular, R.S. 40:4(A)(1)(a) and R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1251 (June 2002).

§1511. Personnel
[formerly paragraph 6:195]

A. The personnel responsible for directing the manufacture and control of the drug shall be adequate in number, and in education, training and experience, or combination thereof, to assure that the drug has the safety, identity, strength, quality and purity that it purports to possess. All personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing and control functions they perform and adequate information concerning the reason for application of pertinent provisions of this Part to their respective functions.

B. [Formerly paragraph 6:196] Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesion that may adversely affect the safety or quality of drugs, shall be excluded from direct contact with drug products until the condition is corrected. All employees shall be instructed to report to supervisory personnel any condition that may have an adverse affect on drug products.

AUTHORITY NOTE: Promulgated in accordance with the provisions of §258(B) of Title 36, and Chapters 1 and 4 of Title 40 of the Louisiana Revised Statutes of 1950. See in particular, R.S. 40:4(A)(1)(a) and R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1251 (June 2002).

§1513. Building Construction
[formerly paragraph 6:197]

A. Buildings shall be maintained in a clean and orderly manner and shall be of a size and construction to comply with the requirements of §§107-109.J of this Part, and of Part XIV (Plumbing) of this Code.

AUTHORITY NOTE: Promulgated in accordance with the provisions of §258(B) of Title 36, and Chapters 1 and 4 of Title 40 of the Louisiana Revised Statutes of 1950. See in particular, R.S. 40:4(A)(1)(a) and R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1252 (June 2002).

§1515. Building Requirements
[formerly paragraph 6:198-1]

A. [Formerly paragraph 6:198-1] Buildings shall provide space for:

1. [Formerly paragraph 6:198-1 (1)] orderly placement of equipment and materials to minimize the possibility of contamination;

2. [Formerly paragraph 6:198-1 (2)] the receipt, storage and withholding from use of components pending sampling, identification and testing prior to release by the materials approval unit for manufacturing or packaging;

3. [Formerly paragraph 6:198-1 (3)] the holding of rejected components prior to distribution to preclude the possibility of their use in manufacturing or packaging procedures for which they are unsuitable;

4. [Formerly paragraph 6:198-1 (4)] the storage of components, containers, packing materials and labeling;

5. [Formerly paragraph 6:198-1 (5)] any manufacturing and processing operation performed;

6. [Formerly paragraph 6:198-1 (6)] any packing or labeling operation;

7. [Formerly paragraph 6:198-1 (7)] storage of finished product;

8. [Formerly paragraph 6:198-1 (8)] control and production laboratory operations.

B. [Formerly paragraph 6:198-2] Provide lighting and ventilation as per §313.A.3 and 4 of this Part, and screening, and when necessary for the intended production or control purposes (for example, the production of sterile products or to prevent antibiotic pollution) provide facilities for positive air pressure, microbiological, dust and temperature controls to:

1. [Formerly paragraph 6:198-2 (1)] minimize contamination of products by extraneous adulterants, including cross contamination of one product with dust particles of ingredients arising from the manufacture, storage or handling of another product;

2. [Formerly paragraph 6:198-2 (2)] provide for storage of drug components, in-process materials, and finished drugs in conformance with stability information as derived under §1705.B of this Code;

3. [Formerly paragraph 6:198-2 (3)] minimize dissemination of microorganisms from one area to another;

4. [Formerly paragraph 6:198-2 (4)] provide locker facilities for employee clothing and belongings. Provide washing facilities equipped with hot and cold water under pressure, delivered through a mixing faucet. Soap and sanitary towels or air dryer shall be provided at each lavatory.

C. [Formerly paragraph 6:198-3] Provide a supply of potable water (Part XIV, Plumbing) under conditions of positive pressure in a plumbing system free of defects that

could cause or contribute to contamination of any drug. Drains shall be a minimum of 4 inches, and where connected directly to a sewer, shall be equipped with traps to prevent back-siphonage.

D. [Formerly paragraph 6:198-4] Provide suitable housing and space for the care of all laboratory animals.

E. [Formerly paragraph 6:198-5] Provide for safe and sanitary disposal of sewage, trash and other refuse within and from the building and immediate premises.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1252 (June 2002).

§1517. Equipment **[formerly paragraph 6:199]**

A. Equipment used for the manufacture, processing, packing, labeling, holding, testing or control of drugs shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction and location to facilitate cleaning, maintenance and operation of its intended purpose. The equipment shall:

1. [Formerly paragraph 6:199-1] be constructed so that all surfaces that come into contact with a drug product shall not be reactive, additive or absorptive so as to alter the safety, identity strength, quality or purity of the drug or its components beyond established requirements;

2. [Formerly paragraph 6:199-2] be constructed so that any substance required for operation of the equipment, such as lubricant or coolants, do not contact drug products so as to alter the safety, identity, strength, quality or purity of the drug or its components beyond the established requirements;

3. [Formerly paragraph 6:199-3] be constructed and installed to facilitate adjustment, disassembly, cleaning and maintenance to assure the reliability of control procedure's uniformity of production and exclusion from the drugs of contamination from previous and current operations that might affect the safety, identity, strength, quality or purity of the drug or its components beyond established requirements;

4. [Formerly paragraph 6:199-4] be of suitable type, size and accuracy for any testing, measuring, mixing, weighing or other processing of storage operations. The regulations in this part permit the use of precision automatic, mechanical or electronic equipment in the production and control of drugs when inspection and checking procedures are used to assure proper performance.

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HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1252 (June 2002).

§1519. Product Production and Quality Control **[formerly paragraph 6:200]**

A. Production and control procedures shall include all reasonable precautions including the following to assure that the drugs produced have the safety, identity, quality, strength and purity they purport to possess:

1. [Formerly paragraph 6:201-1] each significant step in the process, such as selection, weighing and measuring during the various stages of the processing and determination of the finished yield shall be performed by a competent and responsible individual and checked by a second competent and responsible individual; or if such steps in the processing are controlled by precision automatic, mechanical or electronic equipment, their performance is checked. The written record of the significant steps in the process shall be performed by a person having requisite abilities; such identifications shall be recorded immediately following the completion of such steps;

2. [Formerly paragraph 6:201-2] all containers, lines and equipment used during the production of a batch of drugs shall be properly identified at all times to accurately and completely indicate their contents, and when necessary, the stage of processing of the batch;

3. [Formerly paragraph 6:201-3] to minimize contamination and prevent mix-ups, equipment, utensils and containers shall be thoroughly cleaned or sanitized and stored and have previous batch identification removed or obliterated between batches at intervals while production operations are continuing;

4. [Formerly paragraph 6:201-4] precautions shall be taken to minimize microbiological and other contamination in the production of drugs purporting to be sterile, or which by virtue of their intended use should be free from objectionable microorganisms, such as the known common pathogens and others which might affect stability, color or taste;

5. [Formerly paragraph 6:201-5] procedures shall be established to minimize the hazard to any drugs while being manufactured or stored. Such procedures shall meet with the approval of the state health officer;

6. [Formerly paragraph 6:201-6] to assure the uniformity and integrity of products, there shall be in-process controls, such as checking the weights and disintegration times of tablets, the adequacy of mixing, the homogeneity of suspensions and the clarity of solutions. In-process sampling shall be done at intervals.

7. [Formerly paragraph 6:201-7] Representative samples of all dosage form drugs shall be tested to determine their conformance with the specifications of the product before distribution;

8. [Formerly paragraph 6:201-8] review and approval of all production and control records, including packing and labeling, shall be made prior to the release for distribution of

a batch, and records maintained to show this review. A thorough investigation of the failure of a batch to meet any of its specifications shall be undertaken whether or not the batch has been distributed. The investigation shall extend to other batches of the same drug and other drugs that may have been associated with a problem found with that batch. A written record of the investigation shall be made and shall include the conclusion and follow-up;

9. [Formerly paragraph 6:201-9] returned goods shall be identified as such and held. If the conditions under which returned goods have been held, stored or shipped prior to or during their return, or the condition of the product, its container, carton or labeling as a result of storage or shipping cast doubt on the safety, identity, strength, quality or purity of the drug, the returned goods shall be destroyed or subjected to examination or testing to assure the material meets all original standards or specifications before being returned to stock for warehouse distribution or repacking. If the product is neither destroyed nor returned to store, it may be reprocessed provided the final product meets all of its standards and specifications. Records of returned goods shall be maintained and shall indicate the quantity returned, date and actual disposition of the product. If the reason for returned goods implicates associated batches, an appropriate investigation shall be made in accordance with the requirements of §1519.A.8 of this Part;

10. [Formerly paragraph 6:201-10] use of asbestos-containing or other fiber releasing filters:

a. [Formerly paragraph 6:201-10 (1)] filter used in the manufacture, process or packing of components of drug products for parenteral injections in humans shall not release fibers into such products. No asbestos-containing or other fiber-releasing filter may be used in the manufacture, process or packaging of such products unless it is not possible to manufacture that drug product or component without the use of such a filter. Filtration, as needed shall be through a non-fiber-releasing filter. This filter shall be defined as a non-asbestos filter that after the pretreatment such as washing or flushing, will not continue to release fibers into the drug product or component that is being filtered. A fiber is defined as any particle with length at least three times greater than its width;

b. [Formerly paragraph 6:201-10 (2)] if the use of a fiber-releasing filter is required, an additional non-fiber releasing filter or maximum pore size of 0.22 microns (0.45 microns if the manufacturing conditions so dictate) shall subsequently be used to reduce the content of any asbestos-form particle in the drug product or component.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

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§1521. Components

[formerly paragraph 6:202]

A. All components and other materials used in the manufacture, processing and packing of drug products, and

materials necessary for building and equipment maintenance, shall upon receipt be stored and handled in a safe, sanitary and orderly manner to assure safety, purity and strength. Precautions shall be taken to prevent mix-ups and cross-contamination affecting drugs and drug products. Components shall be held from use until they have been identified, sampled and tested for conformance to established specifications and are released by a material approval unit. Controls of components shall include the following.

1. [Formerly paragraph 6:202-1] Each container of component shall be examined visually for damage or contamination prior to use, including examination for breakage of seals, when indicated.

2. [Formerly paragraph 6:202-2] Samples shall be taken from component containers from each lot and shall be subjected to one or more tests to establish their specific identity.

3. [Formerly paragraph 6:202-3] Samples of components liable to contamination with filth, insect infestation or other extraneous contaminants shall be appropriately examined.

4. [Formerly paragraph 6:202-4] Samples of components liable to microbiological contamination shall be subjected to microbiological test prior to use. Such components shall not contain microorganisms that are objectionable in view of their intended use.

5. [Formerly paragraph 6:202-5] Samples of all components intended for use as active ingredients shall be tested to determine their strength in order to assure conformance with specifications approved by the state health officer.

6. [Formerly paragraph 6:202-6] Components which have previously been approved shall be identified and retested as necessary to assure that they continue to meet specifications:

a. [Formerly paragraph 6:202-6 (1)] Components which have been approved shall be handled and stored to guard against contamination or being contaminated by other drugs or components.

b. [Formerly paragraph 6:202-6 (2)] Components which have been approved shall be rotated in such a manner that the oldest stock is used first.

c. [Formerly paragraph 6:202-6 (3)] Rejected components shall be identified and held to preclude their use in manufacturing or processing procedures for which they are unsuitable.

7. [Formerly paragraph 6:202-7] Records shall be maintained for at least two years after distribution has been completed, or one year after the drug's expiration date, whichever is longer. Such records shall include:

a. [Formerly paragraph 6:202-7 (1)] The identity and quantity of the component, the name of the supplier, the supplier's lot number and the date of receipt.

b. [Formerly paragraph 6:202-7 (2)] Examinations and tests performed, and rejected components and their disposition.

c. [Formerly paragraph 6:202-7 (3)] An individual inventory and record for each component used in each batch of drug manufactured or processed.

8. [Formerly paragraph 6:202-8] An identified reserve sample of all active ingredients consisting of at least twice the quantity necessary for all required tests, except those for sterility and determination of pyrogens, shall be retained for at least two years after distribution of the last drug lot incorporating the component has been completed, or one year after the expiration date of this last drug lot, whichever is longer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1253 (June 2002).

§1523. Product Containers and Their Components **[formerly paragraph 6:203]**

A. Specifications, test methods, cleaning procedures and when indicated, sterilization procedures shall be used to assure that containers, closures and other component parts of drug packages are suitable for their intended use. Containers for parenteral drugs, drug products or drug components shall be cleansed with water which has been filtered through a non-fiber releasing filter. Product containers and their components shall not be reactive, additive or absorptive so as to alter the safety, strength, identity, quality or purity of the drug or its components beyond the official or established requirements, and shall provide protection against external factors that can cause the deterioration or contamination of the drug.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1254 (June 2002).

§1525. Laboratory Controls **[formerly paragraph 6:204]**

A. Laboratory controls shall include the establishment of scientifically sound specifications, standards and test procedures to assure that the components, in-processed drugs and finished products conform to standards of identity, strength, quality and purity. Laboratory controls shall include requirements listed in §§1525.A.1-1525.A.10.

1. [Formerly paragraph 6:205-1] The establishment of master records containing specifications for the acceptance of each lot of components, product containers and their components used in drug production and packaging and a description of the sampling and testing procedures used for them. Such records shall also contain provisions for retesting of drug components, product containers and their components which are subject to deterioration.

2. [Formerly paragraph 6:205-2] A reserve sample of all active ingredients as required by §1521.

3. [Formerly paragraph 6:205-3] The establishment of master records containing specifications and a description of sampling procedures for in-process drug preparations.

4. [Formerly paragraph 6:205-4] The establishment of master records containing a description of sampling procedures and appropriate specifications for the finished drug product.

5. [Formerly paragraph 6:205-5] Provisions for checking the identity and strength of a drug product for all active ingredients and for assuring:

a. [Formerly paragraph 6:205-5 (1)] sterility of drugs purported to be sterile; and freedom from objectionable microorganisms (such as the known common pathogens and others which might affect safety, strength and purity) for those drugs which should be so by virtue of their intended use;

b. [Formerly paragraph 6:205-5 (2)] the absence of pyrogens for those drugs purporting to be pyrogen-free;

c. [Formerly paragraph 6:205-5 (3)] minimal contamination of ophthalmic ointment by foreign particles and harsh or abrasive substances;

d. [Formerly paragraph 6:205-5 (4)] that the drug release pattern of sustained-release products is tested by laboratory methods to assure conformance to release specifications.

6. [Formerly paragraph 6:205-6] Provisions for auditing the reliability, accuracy, precision and performance of laboratory instruments and test procedures.

7. [Formerly paragraph 6:205-7] An identified reserve sample of the finished product (stored in the same immediate container-closure system in which the drug is marketed) consisting of at least twice the quantity necessary to perform all the necessary tests, except those for sterility and determination of the absence of pyrogens, shall be stored under conditions consistent with product labeling, and shall be retained for at least two years after distribution has been completed or one year after the expiration date, whichever is longer.

8. [Formerly paragraph 6:205-8] Provisions for retaining complete records of all laboratory data relating to each batch or lot of drug to which they apply. Such records shall be retained for at least two years after distribution has been completed or one year after the drug's expiration date, whichever is longer.

9. [Formerly paragraph 6:205-9] Provisions that animals shall be maintained and controlled in a manner that assures suitability for their intended use. They shall be identified and records maintained to determine the history of use.

10. [Formerly paragraph 6:205-10] Provisions that firms which manufacture non-penicillin products (including certifiable antibiotic products) on the same premises or use the same equipment as that used for manufacturing penicillin products, or that operate under any circumstances that may

be regarded as conducive to contamination of other drugs by penicillin, shall test such non-penicillin products. Such products shall not be marketed if intended for use in man and the product is contaminated with an amount of penicillin equivalent to 0.05 units or more of penicillin AG" per maximum single dose recommended in the labeling of a drug intended for oral use.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1254 (June 2002).

§1527. Stability
[formerly paragraph 6:206]

A. There shall be assurance of the stability of the finished drug products. This stability shall be:

1. [Formerly paragraph 6:206-1] determined by reliable, specific test methods;

2. [Formerly paragraph 6:206-2] determined on products in the same container closure system in which they are marketed;

3. [Formerly paragraph 6:206-3] determined on any dry drug product that is to be reconstituted at the time of dispensing (as directed in its labeling) as well as on the reconstituted product;

4. [Formerly paragraph 6:206-4] recorded and maintained in such a manner that the stability data may be utilized in establishing product expiration dates.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1255 (June 2002).

§1529. Expiration Dating
[formerly paragraph 6:207]

A. To assure that the drug product liable to deterioration meets appropriate standards of identity, strength, quality and purity at the time of use, the label of all such drugs shall have suitable expiration dates which relate to the stability test performed on the product.

1. [Formerly paragraph 6:207-1] Expiration dates appearing on the drug product label shall be justified by readily available data from stability studies such as described in §1527.

2. [Formerly paragraph 6:207-2] Expiration dates shall be related to storage conditions stated on the labeling wherever the expiration date appears.

3. [Formerly paragraph 6:207-3] When the drug is marketed in the dry state for use in preparing a liquid product, the label shall bear expiration date and information for the reconstituted product as well as an expiration date for the product.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1255 (June 2002).

§1531. Packaging and Labeling
[formerly paragraph 6:208]

A. Packaging and labeling operations shall be controlled to assure that only those products that have met the standards and specifications in their master production and control records shall be distributed; to prevent mix-ups between drugs during filling, packaging and labeling operations to assure that correct labels and labeling are employed for the drug and to identify the finished product with a lot or control number that permits determination of the history of the manufacture and control of the batch. An hour, day or shift code is appropriate as a lot or control number for drug products manufactured or processed in continuous production equipment. Packaging and labeling operations shall:

1. [Formerly paragraph 6:208-1] be separated (physically or spatially) from operations on other drugs in a manner so as to avoid mix-ups and minimize cross-contamination. Two or more packaging or labeling operations having drugs, containers or labeling similar in appearance shall not be in process simultaneously on adjacent or nearby lines unless these operations are separated physically or spatially;

2. [Formerly paragraph 6:208-2] provide for an inspection of the facilities prior to use to assure that all drugs and previously used products and labeling materials have been removed;

3. [Formerly paragraph 6:208-3] include the following labeling controls:

a. [Formerly paragraph 6:208-3 (1)] the holding of labels and package labeling upon receipt pending review and proofing against an approved final copy to assure that they are accurate regarding identity, and content before release to inventory;

b. [Formerly paragraph 6:208-3 (2)] the maintenance and storage of each type of label and package labeling representing different products, strength, dosage forms or quantity of contents in such a manner as to prevent mix-ups and provide identification;

c. [Formerly paragraph 6:208-3 (3)] a system for assuring that only current labels and package labeling are retained and that stocks of obsolete package labeling are destroyed;

d. [Formerly paragraph 6:208-3 (4)] restriction of access to labels and package labeling to authorized personnel;

e. [Formerly paragraph 6:208-3 (5)] avoidance of gang printing of cut labels, cartons or inserts when the labels, cartons or inserts are for different products or different strengths of the same products or are of the same size and have identical or similar format and/or color schemes. If gang printing is employed, packaging and labeling operation shall provide for added control procedures. These added controls should consider sheet layout, stacking, cutting and handling during and after printing;

4. [Formerly paragraph 6:208-4] provide for strict control of the package labeling issued for use with the drug. Such issue shall be carefully checked by a competent individual for identity and conformity to the labeling specified in the batch production. Said individual shall reconcile any discrepancy between the quantity of the drug finished and the quantities of labels issued;

5. [Formerly paragraph 6:208-5] provide for examination or laboratory testing of samples of finished product after packaging and labeling to safeguard against any errors in the finished operation and to prevent distribution of any batch until all tests have been met.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1256 (June 2002).

§1533. Records and Reports

[formerly paragraph 6:209-1]

A. To assure uniformity from batch to batch, a master production and control record for each drug product and each batch size of drug product shall be independently checked, reconciled, dated and signed or initialed by a second. The master production and control record shall include:

1. [Formerly paragraph 6:209-1 (1)] the name of the product, description of the dosage form and a specimen of the copy of each label and all other labeling associated with the retail or bulk unit, including copies of such labeling signed or initialized and dated by the person or persons responsible for the approval of such labeling;

2. [Formerly paragraph 6:209-1 (2)] the name and weight or measure of each active ingredient per dosage unit, or per unit of weight or measure of the finished drug, and statement of the total weight or measure of any dosage unit;

3.a. [Formerly paragraph 6:209-1 (3)] a complete list of ingredients designated by names or codes to indicate any special quality characteristic;

b. an accurate statement of the weight or measure of each ingredient, regardless of whether it appears in the finished product. Reasonable variations may be permitted in the amount of components necessary in the preparation in dosage form, provided that provisions for such variations are included in the master production and control record;

c. a statement of theoretical weight or measure at various stages of processing and a statement of theoretical yield;

4. [Formerly paragraph 6:209-1 (4)] a description of the containers, closures and packaging and finishing materials;

5. [Formerly paragraph 6:209-1 (5)] manufacturing and control instructions, procedures and specifications, special notations and precautions to be followed.

B. The batch production and control record shall be prepared for each batch of drug produced and shall include complete information relating to the production and control of each batch. These records shall be retained for at least two years after the batch distribution is complete or at least one year after the batch expiration date, whichever is longer. These records shall identify the specific labeling and lot or control numbers used on the batch, and shall be readily available during such retention period. The batch record shall include:

1. [Formerly paragraph 6:209-2 (1)] an accurate reproduction of the master formula record checked, dated and signed or initialed by a person responsible for the approval of this record;

2. [Formerly paragraph 6:209-2 (2)] a record of each step in the manufacturing, processing, packaging, labeling, testing and controlling of the batch, including dates, individual major equipment and lines employed, specific identification of each batch of components used, weights and measures of components and products used in the course of processing, in-process and laboratory control results and identification and checking each significant step in the operation;

3. [Formerly paragraph 6: 209-2 (3)] a batch number that identifies all the production and control documents relating to the history of the batch and all lot and control numbers associated with the batch;

4. [Formerly paragraph 6:209-2 (4)] a record of any investigation made according to §1533.A.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1256 (June 2002).

§1535. Distribution Records

[formerly paragraph 6:209-3]

A. Finished goods warehouse control and distribution procedures shall include a system by which the distribution of each lot of drug can be readily determined to facilitate its recall if necessary. Records within the system shall contain the name and address of the consignee, date and quantity shipped and lot or control number of the drug. They shall be kept for two years after the batch has been completed or one year after the expiration of the drugs, whichever is longer.

B. [Formerly paragraph 6:209-4] To assure the quality of the product, finished goods warehouse control shall also include a system whereby the oldest stock is distributed first whenever possible.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1256 (June 2002).

§1537. Complaint Files
[formerly paragraph 6:210]

A. Records shall be maintained of all written and oral complaints regarding each product. An investigation of each complaint shall be made in accordance with Part I of this Code. The record of each investigation shall be maintained for at least two years after the distribution of the drug has been completed or one year after the expiration date, whichever is longer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1256 (June 2002).

Chapter 17. Drug Distributors, Drug Wholesalers and Drug Storage Warehouses

§1701. Definitions
[formerly paragraph 6:211]

A. Unless otherwise specifically provided herein, the following words and terms used in this Part of the Sanitary Code, and all other Parts which are adopted or may be adopted, are defined for the purposes thereof as follows:

Drug Wholesaler or Drug Distributor Any person or establishment that distributes drugs other than to the ultimate consumer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1257 (June 2002).

§1703. Permits
[formerly paragraph 6:212]

A. No person shall operate as a drug wholesaler, drug distributor or operate a drug warehouse within the State of Louisiana without first applying for, paying required fee and obtaining a permit to operate issued by the state health officer. Operating without such permit is a violation of this Code.

B. Every establishment regulated by this Part shall have displayed at all times a permit to operate.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1257 (June 2002).

§1705. Buildings
[formerly paragraph 6:213]

A. All buildings shall be maintained in a clean and orderly manner approved by the state health officer and shall be large enough and constructed and located in a way to facilitate cleaning and maintenance of good storage conditions of drugs and drug products.

B. [Formerly paragraph 6:214] All building shall be well lighted and ventilated.

C. [Formerly paragraph 6:215] All floors, walls, ceilings, tables and other fixtures shall be constructed of such materials that they may be readily cleaned.

D. [Formerly paragraph 6:216] All buildings shall be free of flies, rats, mice and other vermin. All insecticides and pesticides used shall be approved by the state health officer.

E. [Formerly paragraph 6:217] All buildings shall provide locker facilities for employee clothing and belongings. Provide washing facilities equipped with hot and cold water under pressure, delivered through a mixing faucet. Soap and sanitary towels or air dryer shall be provided at each lavatory.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1257 (June 2002).

§1707. Premises
[formerly paragraph 6:218]

A. All grounds where buildings are located shall be properly graded to provide a natural drainage, thus preventing an accumulation of stagnant water and other material.

B. [Formerly paragraph 6:219] No litter, waste or refuse shall be allowed to accumulate in and around the building or yards. Waste shall be removed and disposed of in an approved manner

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1257 (June 2002).

§1709. Water Supply
[formerly paragraph 6:220]

A. An ample supply of potable water (Part XII) under pressure shall be provided on the premises for drinking, cleaning, washing or other purposes. Such water supply shall not be connected to any other supply.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1257 (June 2002).

§1711. Records
[formerly paragraph 6:221]

A. Readily retrievable records shall be maintained which will show the disposition of all prescription items. Such records shall be retained for two years.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1257 (June 2002).